



AMENDED ORDER AND DIRECTIVE CONCERNING AdvaGenix (Rockville, Maryland)

No. MDH 2020-08-18-01

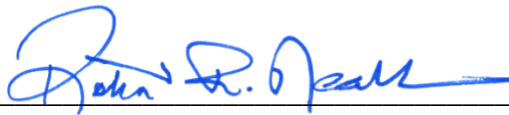
I, Robert R. Neall, Secretary of Health, finding it necessary for the prevention and control of 2019 Novel Coronavirus (“SARS-CoV-2” or “2019-NCoV” or “COVID-19”), and for the protection of the health and safety of residents, staff, and other individuals in Maryland, hereby authorize and order the following actions for the prevention and control of this infectious and contagious disease under the Governor’s Declaration of State of Emergency and Catastrophic Health Emergency. **This Amended Order and Directive replaces and supersedes the Order and Directive Regarding AdvaGenix, dated August 14, 2020.**

Based on the results of a joint federal and state investigation, concluded on August 12, 2020, of the **AdvaGenix** laboratory (also known as “Advanced Genetic Sciences”), 9430 Key West Ave, Suite 130, Rockville, Maryland 20850, Maryland Permit #2540, the preliminary finding of certain improper laboratory and COVID-19 testing procedures that endanger patient health, safety, and welfare, and the imposition of sanctions by the Maryland Department of Health’s (MDH) Office of Health Care Quality (OHCQ), it is hereby ORDERED that the following occur:

1. AdvaGenix shall not collect or process COVID-19 specimens from any COVID-19 specimen collection site in Maryland, unless and until OHCQ authorizes AdvaGenix to resume COVID-19 testing.
2. AdvaGenix shall not represent that it is authorized to conduct COVID-19 testing to the public until OHCQ authorizes AdvaGenix to resume COVID-19 testing.
3. AdvaGenix shall immediately notify all patients that it tested for COVID-19 that the results of those tests are erroneous or questionable and advise the patients to consider alternate testing or retesting, as appropriate. The patient notice must be approved by OHCQ prior to transmittal.
5. AdvaGenix shall place a public notice on its website and any websites with which it is affiliated that it is not certified to provide COVID-19 specimen collection or conduct laboratory analysis of COVID-19 specimens. The public notice shall include information informing patients previously tested for COVID-19 to consider alternative testing or retesting as appropriate.
6. AdvaGenix shall, within 48 hours, provide the MDH Epidemiology Unit and OHCQ with a complete list of all individuals tested, including demographics, contact information, and results of each test (positive, negative, or inconclusive). The information shall be provided to David Blythe, State Epidemiologist, at david.blythe@maryland.gov, and OHCQ at renee.webster@maryland.gov.

7. AdvaGenix shall fully cooperate with all MDH instructions and any further instructions by local health departments in contacting the patients tested.
8. AdvaGenix shall take immediate steps to protect the personal information and protected health information of any patients tested, including but not limited to providing MDH with a detailed explanation of how protected health information is being protected, including copies of all relevant Business Associate Agreements.
9. AdvaGenix shall immediately provide OHCQ with a list of all Maryland entities with which it has contracts to provide COVID-19 testing and the contact information for each entity.

THIS DIRECTIVE AND ORDER IS ISSUED UNDER MY HAND THIS 18TH DAY OF AUGUST 2020 AND IS EFFECTIVE UNTIL SEPTEMBER 13, 2020 UNLESS TERMINATED EARLIER.



Robert R. Neall
Secretary